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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,178	10/28/2003	J. Daniel Raulerson	MED0065	4287
33941	7590	01/26/2009	EXAMINER	
Fox Rothschild LLP Blue Bell 2000 Market Street Tenth Floor Philadelphia, PA 19103			VU, QUYNH-NHU HOANG	
			ART UNIT	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

<b>Application No.</b> 10/695,178	<b>Applicant(s)</b> RAULERSON ET AL.	
<b>Examiner</b> QUYNH-NHU H. VU	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1)  Responsive to communication(s) filed on 10 September 2008.
- 2a)  This action is **FINAL**.
- 2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4)  Claim(s) 29-38 is/are pending in the application.  
4a) Of the above claim(s) 29-33 is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 34-38 is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All   b)  Some \*   c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 11/17/08 & 11/18/08.
- 4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5)  Notice of Informal Patent Application
- 6)  Other: \_\_\_\_\_.

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## DETAILED ACTION

### *Response to Amendment*

Amendment and Request for Continued Examination (RCE) filed on 9/10/08 has been entered.

Claims 34-38 are present for examination.

Claims 29-33 are withdrawn.

### *Drawings*

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the limitation: "the cross-sectional shapes of the first and second proximal end regions are circular" of claim 35 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 35-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. No where in the Specification or Figures discloses the different shapes between cross-sectional shapes of first and second intermediate sections are semicircular and then the cross-sectional shapes changed to circular in the cross-sectional shapes of the first and second proximal end regions.

According to Fig. 2, it only shows that the cross-sectional shapes of the first and second intermediate sections catheter are D-shaped or semicircular. But no where shows that the cross-sectional shapes of the first and second proximal end regions 112, 132 are circulars.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 34-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hobbs et al. (US 7,347,852) in view of Bierman et al. (US 6,663,600).

Hobbs discloses a multiple catheter assembly comprising: a first catheter 10, 20, 30; a second catheter 12, 22, 32; a first and second extension tube (Fig. 2); a first and second intermediate section located at middle region 14, 24 (Figs. 1-5); a hub 16 attached the first and second proximal end region of first and second catheter; the proximal end region/portion of catheter tubes 12 and 14 extend through the hub 16 and proximally beyond the proximal end thereof and connected with other medical devices (Figs. 1-5).

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Hobbs does not show the hub is releasably attachable around the first and second proximal end region of the first and second catheters.

Bierman discloses a catheter device 8 with a separate hub 20 adapted to be releasably attachable to and around the first and the second proximal end regions distally of the proximal end.

It would have been obvious to one having ordinary skill in the art at the time of invention by the applicant to modify the device of Hobbs with the releasably hub, as taught by Bierman, in order to attach or release the hub to the tubes and the patient in a flexible moveable manner.

Regarding claims 35-36, as best as understood, Hobbs discloses the different embodiments with different cross-sectional shaped of lumens. For example: Hobbs discloses the cross-sectional shaped of the first and second proximal end regions is circular (Figs. 4A, 5A); wherein the cross-sectional shaped of the first and second intermediate section of the first and second catheters are semicircular or D-shaped (Fig. 5B). As known that, one skill in the art would recognize the semicircular or D-shaped are similar shapes and performing are equally. Hobbs does not clearly disclose the cross-sectional shaped of the first and second distal end portions of the first and second extend are circular. It would have been an obvious matter of design choice or common sense to provide a tube with cross-sectional with circular shape, since the proximal end of catheter tubes in circular shaped (Fig. 5A). Therefore, the first and second distal end portion of extension tubes is circular shaped to well-fitted with the proximal end of catheter. Furthermore, since applicant has not disclosed that cross-sectional shaped solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the cross-sectional shaped of Hobbs.

Regarding claim 37, Hobbs further discloses the first and second intermediate section of the first and second catheter are splittably joined to each other (Figs. 7-8). As noted that, Figs. 11-12 are different embodiments with Figs. 1-5. However, one skill in the art can apply this concept to other embodiment (col. 6, lines 11-12).

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Claims 34-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ash et al. (US 5,947,953) in view of Bierman (US 6,663,600).

Ash discloses a multiple catheter assembly comprising: a first catheter 26; a second catheter 30; a first and second extension tube 84, 90; a hub 24 attached and around the first and second proximal end region of first and second catheter (Fig. 1); the proximal end region/portion of catheter tubes extend through the hub 24 and proximally beyond the proximal end thereof and connected with other medical devices. Ash shows a cross-sectional shaped of the first and second intermediate sections of the first and second catheter is semicircular (Fig. 4F). Ash further discloses that the configuration in each lumen 28, 32 can be used with other configuration such as oval, circular, elliptical, square, triangular, kidney-bean shaped. The catheter assembly 10 having such luminal configurations will have a varied cross section accordingly (col. 7, lines 30-45). Therefore, one skill in the art would recognize that the device of Ash can be provided with different cross-section shaped (circular or semicircular etc...) at different regions without departing from the spirit of the invention;

Sisley does not show the hub 24 is releasably hub.

Bierman discloses a catheter device 8 with a separate hub 20 adapted to be releasably attachable to and around the first and the second proximal end regions distally of the proximal end.

It would have been obvious to one having ordinary skill in the art at the time of invention by the applicant to modify the device of Ash with the releasably hub, as taught by Bierman, in order to attach or release the hub to the tubes and the patient in a flexible moveable manner.

Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hobbs and Ash et al in view of Bierman et al. and further in view of Casal (US 5,800,414).

Hobbs and Ash in view of Bierman discloses the invention substantially as claimed.

Hobbs discloses the first and second intermediate sections of the first and second catheter are splitably joined to each other (Figs. 11-12) as discussed above.

Ash discloses that the first and second intermediate sections of the first and second catheters are splittably joined to each other (col. 6, lines 20+).

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Hobbs and Ash in view of Bierman does not clearly mention two catheters joined to each other by adhesive.

Cazal discloses a similar device, in which the first and second catheters are splittably joined to each other by adhesive 14 or 20.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Sisley in view of Bierman with two catheters joined to each other by adhesive, as taught by Cazal, in order to join the two catheters.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 34-38 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-37 of copending Application No. 10/974,267.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they device of instant claims are fully disclosed and covered by the claims in the copending application claims.

As noted that, claims 1-37 does not include the hub or an initially separate hub. However, the Applicant admitted that the hub 150 may be omitted is common sense or well-known in the art (see para 0036 of Specification or para 0050 of Application 10/974267). Therefore, it would have been obvious to

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one ordinary skill in the art at the time the invention was made to the releasable hub, since it has been held that omission of an element and its function in a combination where the remaining elements perform the same functions as before involves only routine skill in the art.

### ***Response to Arguments***

Applicant's arguments with respect to claims 34-38 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quynh-Nhu H. Vu whose telephone number is 571-272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu  
Examiner  
Art Unit 3763